



June 28, 2013

VIA ECF

Hon. Douglas E. Arpert, U.S.M.J.
U.S. District Court for the District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

**RE: *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*,
Civ. Action No. 3:11-cv-02317 (consolidated for discovery)**

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Dear Judge Arpert:

We, along with Covington & Burling and Vinson & Elkins represent Plaintiffs AstraZeneca AB, AstraZeneca LP, KBI-E Inc., and Pozen Inc. (collectively, "Plaintiffs") in this Hatch-Waxman litigation involving the patents related to the product Vimovo[®]. DRL has filed two separate ANDAs relating to those patents. Those filings came nearly two years apart and have resulted in two separate Hatch-Waxman cases. Civil Case No. 3:11-cv-2317 ("DRL I") was filed on April 21, 2011. Civil Case No. 3:13-cv-91 ("DRL II") is more recent, filed on January 4, 2013.

This letter responds to DRL's June 26, 2013, letter in which DRL challenged Plaintiffs' service of Responses to Invalidity Contentions in DRL II under L. Pat. R. 3.4A and 3.6(i) (the "Responses"). In their letter, DRL suggests entry of an order striking Plaintiffs' Responses. In this letter, we suggest the entry of an order granting summary judgment against DRL on its affirmative defense of patent invalidity.

Plaintiffs served their Responses to rebut DRL's allegations that the claims of U.S. Pat. No. 6,929,907 ("the '907 Patent") are invalid. DRL certified to the FDA that the claims of the '907 Patent were, *inter alia*, invalid in connection with its second ANDA, and detailed its invalidity allegations in its November 20, 2012, Notice Letter to Plaintiffs. Plaintiffs, in their Complaint, requested that the Court resolve that dispute by entering judgment that the claims of the patents-in-suit, including the '907 Patent, are valid. See Dkt. 1. DRL, in turn, pleaded invalidity of the '907 Patent as an affirmative defense in its Answer.

Despite the dispute over the validity of the '907 Patent, DRL did not serve invalidity contentions to support its defense or to rebut Plaintiffs' request for judgment. DRL provided no explanation at the time for its failure to do so.

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Plaintiffs served their Responses to rebut DRL's allegations of invalidity "to the extent DRL intends to rely on or incorporate by reference its Invalidity Contentions served in DRL I in this case." Responses at 1. Shortly after Plaintiffs served their responses, DRL informed Plaintiffs that DRL had decided not to serve invalidity contentions in this case, and DRL's letter to the Court likewise states that it has made a "decision to forgo any invalidity contentions" in this case.

If DRL's adamant representation that it has decided not to put forward evidence of invalidity in this case can be taken at face value, the Court should enter summary judgment in Plaintiffs' favor on DRL's affirmative defense of invalidity. Patent claims are presumed valid and may only be proven invalid by clear and convincing evidence. *Robotic Visions Sys., v. View Eng'g., Inc.*, 189 F.3d 1370, 1377 (Fed. Cir. 1999). Without any evidence to support its affirmative defense of invalidity, DRL cannot prevail on that defense, and Plaintiffs are entitled to summary judgment. *Celotex Corp. v. Catrett*, 477 U.S. 317, 477-78 (1986) ("One of the principal purposes of the summary judgment rule is to isolate and dispose of factually unsupported claims or defenses."). Accordingly, Plaintiffs are filing today and providing with this letter a motion for summary judgment that the claims of the '907 Patent are not invalid.

Summary judgment on the issue of validity in this case will preclude DRL from litigating the same issue in DRL I. "When an issue of fact or law is actually litigated¹ and determined by a valid and final judgment, and the determination is essential to the judgment, the determination is conclusive in a subsequent action between the parties,² whether on the same or a different claim." *Nat'l R.R. Passenger Corp. v. Pa. Pub. Util. Comm'n*, 288 F.3d 519, 525 (3rd Cir. 2002) (quoting Restatement (Second) of Judgments § 27 (1980)).

It may be that DRL wants to be taken at its word that it does not contest the validity of the patent and, presumably, is prepared to have judgment entered. That judgment may moot the entire issue in both cases.

¹ "When an issue is properly raised, by the pleadings or otherwise, and is submitted for determination, and is determined, the issue is actually litigated within the meaning of this Section. An issue may be submitted and determined on . . . a motion for summary judgment A determination may be based on a failure of . . . proof." Restatement (Second) of Judgments § 27 cmt. D (1980).

² "If two actions which involve the same issue are pending between the same parties, it is the first final judgment rendered in one of the actions which becomes conclusive in the other action, regardless of which action was brought first." Restatement (Second) of Judgments § 27 cmt. 1 (1980)); *see also id.* § 14 ("For purposes of res judicata, the effective date of a final judgment is the date of its rendition, without regard to the date of commencement of the action in which it is rendered or the action in which it is to be given effect.")

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Now, it may be that DRL decided to try for some strategic or tactical advantage in the DRL II case by not raising invalidity contentions. Rather, mindful that Your Honor had denied Plaintiffs' request to amend its Responses to DRL's invalidity contentions in the earlier DRL I case, the defendant may have hoped to prevent Plaintiffs from presenting the full response in DRL II: a case that came about because DRL elected to file a second ANDA challenging the same patents. It was DRL's decision that resulted in the second case (DRL II). If DRL is not willing to consent to judgment on validity it should not be allowed to preclude a full defense of the validity of the patents in both cases.

If DRL is seeking some strategic advantage by, in effect, relying on its DRL I invalidity contentions and invalidity defense for the DRL II case without giving Plaintiffs an opportunity to provide the responses to those contentions—as required under the Court's Local Rules—then Plaintiffs should have an opportunity to provide their Responses. DRL chose to file a second ANDA and chose to raise the issue of validity in the ensuing case, aware that these choices would lead to an opportunity, not only for itself to raise new invalidity contentions or rely on those served in DRL I, but also for Plaintiffs to respond.

Perhaps recognizing this issue, on page 2 of its letter, DRL recognizes that the second action represents changed conditions and arguably would warrant application of the Responses to both cases. We agree. The filing of the second case following from DRL's decision to file a second ANDA is a changed circumstance that provides good cause for amending the Responses in DRL I. Plaintiffs have timely provided their Responses, and DRL cannot now argue that it will be prejudiced by alleged delay in Plaintiffs' Responses as it did in its opposition to Plaintiff's earlier motion for leave to amend in DRL I. The new case is just getting underway, and the parties have now largely agreed to a schedule to start and finish fact and expert discovery. The Responses in DRL II should stand and Amendment in DRL I is appropriate under all the present circumstances.

Respectfully submitted,

s/John E. Flaherty

John E. Flaherty

cc: Counsel of Record (via email)